

# Notice of Allowability

Application No.

10/521,013

Examiner

Julie Ha

Applicant(s)

MUHLRADT ET AL.

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Amendment to After Non-final rejection filed on July 06, 2007.

2. ☒ The allowed claim(s) is/are 1-9 and 11-16.

3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some\* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_

4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material

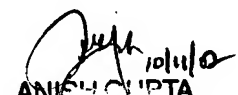
5. ☐ Notice of Informal Patent Application

6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_

7. ☒ Examiner's Amendment/Comment

8. ☐ Examiner's Statement of Reasons for Allowance

9. ☐ Other \_\_\_\_\_

  
ANISH GUPTA  
PRIMARILY EXAMINER

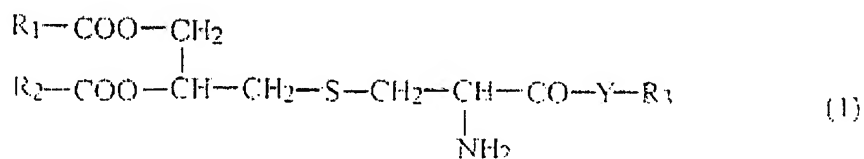
**EXAMINER'S AMENDMENT**

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.
2. Authorization for this examiner's amendment was given in a telephone interview with Ruth E. Tyler-Cross on October 4, 2007.
3. Applicant has requested 2 months extension and this is acknowledged.
4. Amendment After Non-final rejection filed on July 06, 2007 is acknowledged.
5. Claim 10 has been cancelled and new claims 11-16 have been added. Claims 1-9 and 11-16 are allowed.

Claims 1, 7 and 14-16 have been amended as follows:

Claim 1:

A bisacyloxypropylcysteine conjugate according to formula (I),



where

R<sub>1</sub> and R<sub>2</sub> can be identical or different and are C<sub>8</sub>-C<sub>22</sub> alkyl, alkenyl or alkynyl fatty acid radicals which are bonded by way of the carboxyl group;

Y = -NH-, -O-, -S-, or -OCO-;

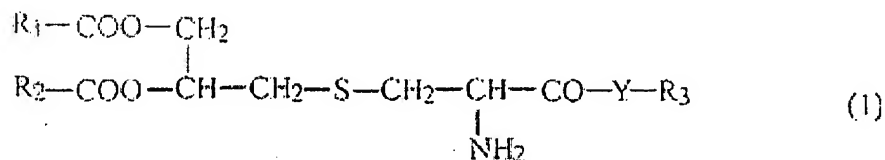
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$R_3$  is a covalently bonded polyethylene glycol (polyoxyethylene)-(CH<sub>2</sub>-CH<sub>2</sub>-O)<sub>m</sub>-CH<sub>2</sub>-CH<sub>2</sub>-X,

where X = OR O(R), N[R]<sub>2</sub> N(R)<sub>2</sub>, SR S(R) or COOR COO(R), and

R (R) = H, benzyl-, or C<sub>1-6</sub> C<sub>1-6</sub> alkyl, where, when X = N[R]<sub>2</sub> N(R)<sub>2</sub>, the [R] (R) groups can be identical or different.

Claim 7: A pharmaceutical composition, comprising a bisacyloxypropylcysteine conjugate according to formula (1),



where

$R_1$  and  $R_2$  can be identical or different and are C<sub>8</sub>-C<sub>22</sub> alkyl, alkenyl or alkynyl fatty acid radicals which are bonded by way of the carboxyl group;

Y = -NH-, -O-, -S-, or -OCO-;

$R_3$  is a covalently bonded polyethylene glycol (polyoxyethylene)-(CH<sub>2</sub>-CH<sub>2</sub>-O)<sub>m</sub>-CH<sub>2</sub>-CH<sub>2</sub>-X,

where X = OR O(R), N[R]<sub>2</sub> N(R)<sub>2</sub>, SR S(R) or COOR COO(R), and

[R] (R) = H, benzyl-, or C<sub>1-6</sub> C<sub>1-6</sub> alkyl, where, when X = N[R]<sub>2</sub> N(R)<sub>2</sub>, the [R] (R) groups can be identical or different.

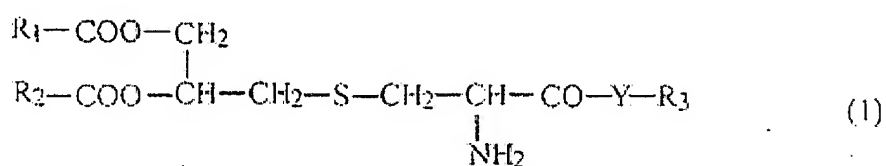
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Claim 14: A method of stimulating an immune response to an antigen in an animal or human, comprising the step of

simultaneously administering to the animal or human

the antigen; and

a bisacyloxypropylcysteine conjugate according to formula (1),



where

$R_1$  and  $R_2$  can be identical or different and are  $\text{C}_8$ - $\text{C}_{22}$  alkyl, alkenyl or alkynyl fatty acid radicals which are bonded by way of the carboxyl group;

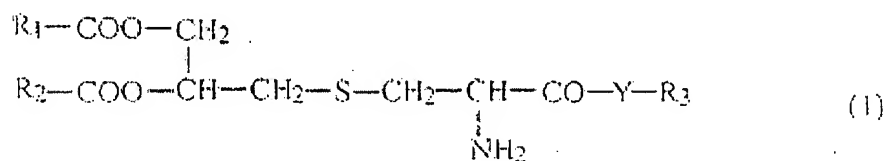
$\text{Y} = -\text{NH}-, -\text{O}-, -\text{S}-, \text{ or } -\text{OCO}-;$

$R_3$  is a covalently bonded polyethylene glycol (polyoxyethylene)- $(\text{CH}_2-\text{CH}_2-\text{O})_m-\text{CH}_2-\text{CH}_2-\text{X},$

where  $\text{X} = \text{OR}, \text{O}(\text{R}), \text{N}[\text{R}]_2, \text{N}(\text{R})_2, \text{SR}, \text{S}(\text{R}), \text{ or } \text{COOR}, \text{COO}(\text{R}),$  and

$\text{R}, (\text{R}) = \text{H}, \text{ benzyl-}, \text{ or } \text{C}_{4-6} \text{ C}_{1-6} \text{ alkyl},$  where, when  $\text{X} = \text{N}[\text{R}]_2, \text{N}(\text{R})_2,$  the  $[\text{R}], (\text{R})$  groups can be identical or different.

Claim 15: A bisacyloxypropylcysteine conjugate according to formula (1),



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where

$R_1$  and  $R_2$  can be identical or different and are  $C_8$ - $C_{22}$  alkyl, alkenyl or alkynyl fatty acid radicals which are bonded by way of the carboxyl group;

$Y = -NH-$ ,  $-O-$ ,  $-S-$ , or  $-OCO-$ ;

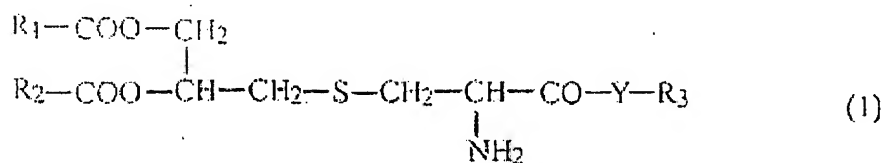
$R_3$  is a covalently bonded polyethylene glycol (polyoxyethylene)-(CH<sub>2</sub>-CH<sub>2</sub>-O)<sub>m</sub>-CH<sub>2</sub>-CH<sub>2</sub>-X,

where  $X = OR$ ,  $O(R)$ ,  $N[R]_2$ ,  $N(R)_2$ ,  $SR$ ,  $S(R)$  or  $COOR$ ,  $COO(R)$ , and

$R$  ( $R$ ) = H, benzyl-, or  $C_{1-6}$   $C_{1-6}$  alkyl, where, when  $X = N[R]_2$ ,  $N(R)_2$ , the  $[R]$  ( $R$ ) groups can be identical or different,

and wherein said bisacyloxypropylcysteine conjugate is a S-[2,3-bis(acyloxy)-(2S)-propyl]-L-cysteinylcarboxypolyethylene glycol.

Claim 16: A bisacyloxypropylcysteine conjugate according to formula (1),



where

$R_1$  and  $R_2$  can be identical or different and are  $C_8$ - $C_{22}$  alkyl, alkenyl or alkynyl fatty acid radicals which are bonded by way of the carboxyl group;

$Y = -NH-$ ,  $-O-$ ,  $-S-$ , or  $-OCO-$ ;

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$R_3$  is a covalently bonded polyethylene glycol (polyoxyethylene)-(CH<sub>2</sub>-CH<sub>2</sub>-O)<sub>m</sub>-CH<sub>2</sub>-CH<sub>2</sub>-X,

where X = OR, O(R), N(R)<sub>2</sub>, SR, S(R) or COOR, COO(R), and

R (R) = H, benzyl-, or C<sub>1-6</sub> C<sub>1-6</sub> alkyl, where, when X = N(R)<sub>2</sub>, the (R) groups can be identical or different,

and wherein said bisacyloxypropylcysteine conjugate is a S-[2,3-bis(acyloxy)-(2R)-propyl]-L-cysteinylcarboxypolyethylene glycol.

### Conclusion

6. Claims 1-9 and 11-16 are allowed. The bisacyloxypropylcysteine conjugates of the instant application are both novel and unobvious over art of record.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie Ha whose telephone number is 571-272-5982.

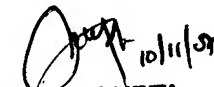
The examiner can normally be reached on Mon-Fri, 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Julie Ha  
Patent Examiner  
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PRIMARY EXAMINER